Documentation for Approval to use the Discrete Analyzer

The following items must be provided to the regulated laboratory by the discrete analyzer manufacturer. Once received, these items must be kept on file by the laboratory so that they are available for review if requested.

- 1) Provide a copy of the modified method that shows how each step of the underlying approved method has been modified. This information can be presented in a two-column comparison format showing the original step and the modified step side by side. The analytical range, equipment, reagent preparation, standard preparation, and final reagent ratios must be addressed.
- Provide a copy of data comparing modified method performance to the approved method. A typical calibration curve, method detection limit (MDL) study, precision, and accuracy data must be submitted.

The following items must be provided to this Office by the regulated laboratory:

- 1) A copy of the application form documenting the methods and analytes that the laboratory will analyze on the discrete analyzer.
- 2) Standard Operating Procedure for each method that the laboratory will use with the discrete analyzer.
- 3) Method Detection Limit (MDL) Studies for each analyte. This procedure is described in 40 CFR Part 136 Appendix B. An example MDL summary form is attached for your convenience. Please also include the raw data (copies of the computer printouts for the MDL analysis sequence) in addition to sample preparation records and analysis logs.
- 4) Initial Demonstration of Capability (IDOC) Study. Where not dictated in the approved EPA Method, analyze four replicates of a standard. Calculate the average percent recovery and the standard deviation. An example IDOC summary form is enclosed for your convenience. Please also include the raw data (copies of the computer printouts for the IDOC analysis sequence) in addition to sample preparation records and analysis logs.
- 5) Initial calibration data (including raw data and analysis run logs) used to quantitate the MDL and IDOC data.
- 6) Instrument operating conditions and run logs for each analysis sequence submitted.

<u>Recommended Documentation</u>: In reference to the EPA memo dated April 2, 2007 concerning discrete analyzers, a study verifying the analysis results from the approved method versus the discrete analyzer method using actual effluent samples should be performed. A minimum of seven samples collected on separate days from each source is strongly suggested. The study data is not required to be submitted, but should be kept on file by the laboratory so that it is available to the client. If there are any changes to the effluent sample, the study should be repeated and documented to ensure the equivalency is maintained.

Please note that if the method intended for use with the discrete analyzer is not already on the laboratory's list of certified parameters, the laboratory must request additional parameter certification. To do this, a complete application package must be submitted. If you need a complete application package or assistance in completing one, please contact the Office of Environmental Laboratory Certification at (803) 896-0970.